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first instrument including a lumen for aspiration of cataract tissue and irrigation fluid from said lens capsule; and

a second instrument having a shaft for inserting into the lens capsule and a tool tip extending transverse to said shaft for manipulating the cataract as the cataract is being removed, said second instrument having an irrigation port for introducing the irrigation fluid into said lens capsule.

## 2. (Cancelled)

- 3. (Previously Amended) The apparatus according to claim 1 wherein said shaft includes a shaft lumen therethrough for delivering the irrigation fluid to said irrigation port.
- 4. (Previously Amended) The apparatus according to claim 1 wherein said second instrument comprises a conduit, attached to said shaft, for delivering the irrigation fluid to said irrigation port.
- 5. (Original) The apparatus according to claim 1 wherein said second instrument comprises a plurality of irrigation ports for introducing the irrigation fluid into said lens capsule.
- 6. (Currently Amended) The apparatus according to claim 2—1wherein the tip comprises a solid hook.
- 7. (Currently Amended) The apparatus according to claim 2-1 wherein the tip comprises a solid blade.

8. (Currently Amended) Apparatus for the removal of lens tissue, said apparatus comprising, in combination:

a first instrument, including a vibrated needle for inserting into a lens capsule and removing a cataract therein, the first instrument including a lumen therethrough for aspiration of emulsified cataract tissue and irrigation fluid from said lens capsule; and

a second instrument having a shaft for inserting into the lens capsule and a tool tip extending transverse to said shaft for manipulating the cataract as the cataract is being removed, said second instrument having an irrigation port for introducing the irrigation fluid into said lens capsule.

## 9. (Cancelled)

- 10. (Previously Amended) The apparatus according to claim 8 wherein said shaft includes a shaft lumen therethrough for delivering the irrigation fluid to said irrigation port.
- 11. (Previously Amended) The apparatus according to claim 8 wherein said second instrument comprises a conduit, attached to said shaft, for delivering the irrigation fluid to said irrigation port.
- 12. (Original) The apparatus according to claim 8 wherein said second instrument comprises a plurality of irrigation ports for introducing the irrigation fluid into said lens capsule.

13. (Currently Amended) The apparatus according to claim 9-8 wherein the tip comprises a hook.

- 14. (Currently Amended) The apparatus according to claim 9-8 wherein the tip comprise a blade.
- 15. (Currently Amended) Apparatus for the phacoemulsification of lens tissue, said apparatus comprising, in combination:

a first instrument, including an ultrasonically vibrated needle for inserting into a lens capsule and emulsifying a cataract therein, the needle including lumen therethrough for aspiration of emulsified cataract tissue and irrigation fluid from said lens capsule through a primary aspiration port defined by an end of said lumen; and

a second instrument having a shaft for inserting into the lens capsule and a tool tip extending transverse to said shaft for manipulating the cataract as the cataract is being emulsified, said second instrument having an irrigation port for introducing the irrigation fluid into said lens capsule.

## 16. (Cancelled)

- 17. (Previously Amended) The apparatus according to claim 15 wherein said shaft includes a shaft lumen therethrough for delivering the irrigation fluid to said irrigation port.
- 18. (Previously Amended) The apparatus according to claim 15 wherein said second instrument comprises a

conduit, attached to said shaft, for delivering the irrigation fluid to said irrigation port.

- 19. (Original) The apparatus according to claim 15 wherein said second instrument comprises a plurality of irrigation ports for introducing the irrigation fluid into said lens capsule.
- 20. (Currently Amended) The apparatus according to claim 16-15 wherein the tip comprises a solid hook.
- 21. (Currently Amended) The apparatus according to claim 16-15 wherein the tip comprises a solid blade.
- 22. (New) Apparatus for the removal of lens tissue, said apparatus comprising, in combination:
- a first instrument for inserting into a lens capsule and removing a cataract therein, the first needle including a lumen for aspiration of cataract tissue and irrigation fluid from said /lens capsule;
- a second instrument having a shaft for inserting into the lens capsule, said second instrument having an irrigation port for introducing the irrigation fluid into said lens capsule;
- a plurality of tool tips for manipulating the cataract as the cataract is being removed; and
- a coupling medium for removably coupling each of said plurality of tool tips to said shaft.
- 23. (New) The apparatus according to claim 22 wherein each tool tip is mounted transverse to said shaft.

- 24. (New) The apparatus according to claim 23 wherein at least one of said plurality of tool tips comprises a solid blade.
- 25. (New) The apparatus according to claim 23 wherein at least one of said plurality of tool tips comprises a solid hook.
- 26. (New) The apparatus according to claim 22 wherein said shaft includes a shaft lumen therethrough for delivering the irrigation fluid to said irrigation port.
- 27. (New) The apparatus according to claim 22 wherein said second instrument comprises a conduit, attached to said shaft, for delivering the irrigation fluid to said irrigation port.

## REMARKS

This request for continued examination is being made in response to a final Office Action for the subject application mailed May 28, 2003.

In the final Office Action, the Examiner objected to the specification due to the presence of a reference to the subject application as being a continuation-in-part. This insertion was inadvertent and the present amendment eliminates the paragraph beginning on line 4 on page 1.

Claims 6, 7, 13, 14, 20 and 21 have been objected to by the Examiner in view of incorrect dependency. The

present amendment to those claims is made to overcome this objection.

Claims 6 and 7 have been rejected by the Examiner under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner notes that claims 6 and 7 recite the limitation "tip" which has no antecedent basis. The present amendment is made to provide the proper antecedent basis.

In addition, the claims have been amended to define the tool tip as extending transverse to the shaft. This facilitates manipulation of the cataract as the cataract is being removed and support for this amendment is easily seen in Figures 5-8.

In addition, claims 22-27 have been added to define the apparatus in accordance with the present invention as including a plurality of tool tips for manipulating the cataract as the cataract is being removed and a coupling medium for removably coupling each of the plurality of tool tips to the shaft. Support for this amendment may be found in the original specification on page 9, beginning at line 19. Accordingly, no new matter has been added by the present amendment.

Claims 1, 3, 4, 7, 8, 10, 11, 15, 17, 18, 19, and 21 have been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 3,736,938 to Evvard. In this rejection, the Examiner has stated that the second

instrument comprises a tool tip, that is, a distal end of element 24, which is capable of being used to manipulate a cataract as the cataract is being removed. The Examiner considers the very tip of the needle as a "blade". The Examiner also concludes that since the shaft 24 is used to deliver a fluid, it inherently has a lumen. As shown this lumen must pass through the very tip of the needle.

It is well known that anticipation is established only when a single prior art referenced discloses, expressly or under principles of inherency, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc. 221 USPQ 385 (Fed. Cir. 1994).

In addition, the Applicants submit that anticipation must meet strict standards, and unless all of the same elements are found in exactly the same situation and united in the same way to form identical function in the single prior art reference, there is no anticipation. <u>Tights</u>, Inc. v. Acme-McCrary Corp. et al. 191 USPQ 305 (CAFC 1996).

With this criteria in mind, it is clear there is no anticipation of the transversely mounted tip of the present invention by the Evvard, et al. reference. Further, with specific regard to claim 7, the present apparatus is defined as including a tip which comprises a solid blade. Clearly, if the very tip of the needle is a "blade" as asserted by the Examiner, this blade cannot be solid in view of the lumen passing therethrough.

Accordingly, in view of the present amendment to the claims, the Applicants submit the rejection of claims 1, 3,

4, 7, 8, 10, 11, 15, 17, 18, 19 and 21 under 35 USC 102(b) on the basis of the Evvard, et al. reference is not sustainable. The Examiner is respectfully requested to withdraw this rejection.

Claims 1, 3, 4 and 6 have been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 5,569,279 to Rainin. In this rejection, the Examiner states that Rainin discloses an instrument for the removal of lens tissue comprising a first instrument 100, a second instrument 50 having a tool 12 and a port comprising a distal end of the second instrument.

The aspiration tube 100 does not anticipate the structure of the first instrument now defined in claim 1 for fragmenting and removing a cataract. Specifically, with reference to column 5 at line 34 of Rainin, the aspiration tube 100 is inserted into the capsule 20 to remove biological matter 16 from the interior 28 of the capsule 20 following abrasion of the same from the capsule 20.

Thus, it is clear that the aspiration tube 100, identified by the Examiner as the first instrument, does not have structure which functions in a manner similar to the first instrument of the present invention for fragmenting cataract tissue. Accordingly, the Applicants submit that rejection of claims 1, 3, 4, and 6 under 35 USC 102(b) on the basis of the Rainin reference is not sustainable and the Examiner is respectfully requested to withdraw this rejection.

Claim 5, 12 and 19 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Evvard in view of U.S. 5,562,640 to McCabe, et al. The Examiner recognizes that Evvard, et al. fails to disclose plurality of irrigation ports in the irrigation instrument and therefore turns to McCabe for teaching the use of a endoscopic surgical generic instrument used in irrigation/aspiration of a surgical site having irrigation channel comprising a plurality of holes. surgical instrument McCabe shows a generic plurality of ports, there is no teaching or suggestion of any structure similar to the apparatus of the present invention for fragmenting and removing a cataract. is there structure teaching a second tool having a shaft for inserting into a lens capsule and a tool tip extending transverse to the shaft for manipulating the cataract as the cataract is being removed.

Since McCabe, et al. is totally silent with regard to this structure the Examiner has not made a prima facie case in the combination of the Evvard, et al. and McCabe, et al. references. Withdrawal of the rejection of claims 5, 12 and 19 under 35 USC 103(a) is respectfully requested.

Claims 8-11, 13, 15, 17, 18 and 20 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Rainin in view of Evvard, et al. The Examiner acknowledges that Rainin is silent with regard to the use of ultrasonically vibrated to more efficiently brake up the cataract and concludes it would have been obvious to one of ordinary skill at the art at the time the invention was

made to apply ultrasonic vibratory energy to the second instrument 50 to more efficiently brake-up a cataract.

The Applicants submit that this combination is in operable. The device 10a of Rainin includes an element 12 with a resilient body 14 having an outer surface 16 which is intended for braiding biological material 16 from a membrane surface 18, see column 3, line 66-66. The Applicants submit that if this resilient body is vibrated at ultrasonic frequencies, there would be no effective fragmenting or emulsification of lens because the resilient nature of the body 14 would dissipate any ultrasonic energy.

Further, if ultrasonic energy is applied to the tube 100, it would have no effect since, according to the teachings of Rainin, the aspiration tube 100 is inserted into the capsule 20 to remove biological matter 16 from the interior 28 to the capsule 20 following abrasion of the same from the capsule 20. Accordingly, it makes no sense to vibrate the aspiration tube 100 of Rainin when it is used to remove already abraded material.

In view of the arguments hereinabove set forth and amendment to the claims and specification, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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7/24/03

WALTER A. HACKLER REG. NO. 27,792